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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/950,003	09/12/2001	Pasqua Oreste	MARGI 27 P1	9777

23599 7590 09/14/2006

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EXAMINER

KRISHNAN, GANAPATHY

ART UNIT PAPER NUMBER

1623

DATE MAILED: 09/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	09/950,003		ORESTE ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Ganapathy Krishnan		1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 03 July 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 14-34,38-53,56-62,64,66,68 and 70 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14-34,38-53,56-62,64,66,68 and 70 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

The After Final Amendment filed 7/3/2006 has been received, entered and carefully considered. The following information provided in the amendment affects the instant application:

1. Claims 1-13, 35-37, 54-55, 63, 65, 67, 69 and 71-77 have been canceled.
2. Claims 14, 17 and 56 have been amended.
3. Remarks drawn to priority claim and rejections under double patenting.
4. Declaration under 37 CFR 1.132 signed by Oreste and Zopetti.

Claims 14-34, 38-53, 56-62, 64, 66, 68 and 70 are pending in the case.

The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

The finality of the previous office action mailed 5/2/2006 has been withdrawn and the following new rejections are made of record.

#### ***Priority***

Applicants argue that the instant application has been limited to claims, which cannot obtain the benefit of the Italian Application MI2000A00065. Applicants have to formally withdraw the priority claim to the Italian Application.

#### ***Double Patenting***

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same

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invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 38-62 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 14-36 of copending Application No. 11/030156 ('156 application).

This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claims 14-34, 38-53, 56-62, 64, 66, 68 and 70-77 are provisionally rejected under 35 USC 101 as claiming the same invention as that of claims 16-74 of copending application No. 10/240606 ('606 application) maintained in the previous office action has been rendered moot due to cancellation of claims 16-74 in copending application No. 10/240606 ('606 application).

Claims 12-13 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4 and 13-14 of the copending application No. 10/240606 ('606 application) maintained in the previous office action has been rendered moot by cancellation of instant claims 12-13.

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The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 14, 15, 17, 20-22 and 24 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 4-6 and 10 of copending Application No. 10/240606 (‘606 application). Although the conflicting claims are not identical, they are not patentably distinct from each other because:

Instant claims 14 and 17 are drawn to a process of preparation of K5 glycosaminoglycans comprising (i) N-deacetylation/N-sulfation of the K5 polysaccharide; (ii) partial epimerization of C5 carboxyl group; (iii) oversulfation; (iv) selective O-desulfation; (v) optional 6-O-sulfation and (vi) N-sulfation wherein the selective O-desulfation step comprises reacting the product from step iii with methanol/dimethyl sulfoxide for a time period of 135-165 minutes. Instant claim 17 recites pretty much the same steps with recitations of epimer ratios and enzyme for the epimerization step and time and temperature for O-sulfation step after converting it to a salt and

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the time and temperature for the 6-O-sulfation. The same steps are recited in claim 4 of the copending '606 application.

Instant claims 20-22 and 24 recite limitations drawn to the type of enzyme used in the epimerization step, presence of specific divalent cations and flow rate of the solution during the epimerization. These limitations are also recited in claims 4-6 and 10 of the copending '606 application.

It would have been obvious to one of ordinary skill in the art at the time the invention was made that the instant claims 14, 15, 17, 20-22 and 24 are substantially overlapping with claims 4-6 and 10 of the copending '606 application.

One of ordinary skill in the art would be motivated to use the process as instantly claimed since the basic process steps are the same and would know that the steps would work equally well using any epimerizing enzyme.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 14, 15, 17, 20-32, 64, 66, 68 and 60 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 4-6, 9-13 and 37-40 of copending Application No. 11/030156 ('156 application). Although the conflicting claims are not identical, they are not patentably distinct from each other because:

Instant claims 14 and 17 are drawn to a process of preparation of K5 glycosaminoglycans comprising (i) N-deacetylation/N-sulfation of the K5 polysaccharide; (ii) partial epimerization of C5 carboxyl group; (iii) oversulfation; (iv) selective O-desulfation; (v) optional 6-O-sulfation

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and (vi) N-sulfation wherein the selective O-desulfation step comprises reacting the product from step iii with methanol/dimethyl sulfoxide for a time period of 135-165 minutes. Instant claim 15 is drawn to the method of claim 14 wherein the time period of methanol/dimethyl sulfoxide treatment is 150 minutes. Instant claim 17 recites pretty much the same steps with recitations of epimer ratios and enzyme for the epimerization step and time and temperature for O-sulfation step after converting it to a salt and the time and temperature for the 6-O-sulfation. Instant claim 20 is drawn to the epimerization step wherein glucuronosyl C5 epimerase enzyme is used in solution or in immobilized form in the presence of divalent cations. These same limitations are seen in claims 4 and 11 of the '156 application.

The limitations recited in instant claims 17, 21-32, 64, 66, 68 and 70 are seen in claims 12, 6, 5, 9, 10, 13, 37, 38, 39 and 40 of the '156 application.

It would have been obvious to one of ordinary skill in the art at the time the invention was made that the instant claims 14, 15, 17, 20-32, 64, 66, 68 and 60 are substantially overlapping with claims 4-6, 9-13 and 37-40 of copending '156 application.

One of ordinary skill in the art would be motivated to use the process as instantly claimed since the basic process steps are the same and would know that the steps would work equally well

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Response to Applicants Arguments***

The Declaration signed by Oreste and Zopetti has been considered. Applicants argue that the feature that distinguishes the process of instant claims 14-34 from that of the '606 application is the selective O-desulfation step, which comprises treating the oversulfated product obtained at the end of step (iii) with a mixture of methanol/dimethyl sulfoxide for a period of 135 to 165 minutes and the '606 application recites a time period of 1-8 hours for the same treatment. The '606 application does not recite a preferred time period for this step. The product obtained by the said treatment for 135-165 minutes also has high activity. This is an unexpected result, which is not obvious according to the applicants.

This argument is not found to be persuasive.

Tables 2 and 4 in the Declaration show the coagulation parameters for the product obtained and the results for 2.5 hours for the said treatment have been highlighted. If one looks at the results provided for the coagulation parameters in Table 2 of Publication US 2004/0146994 ('994 publication; publication of the 10/240606 application) it can be seen that the coagulation parameters for two hours (closer to the parameters for the instantly claimed 2.5 hours) is close to the parameters of the instant product. Moreover, the '994 publication gives examples 1-11 which range from 2 to 4 hours for the said treatment time and it can be seen that depending on the time of the said treatment there is a change in the coagulation parameters. Based on this observation one of ordinary skill in the art would expect the parameters to change with the time period for the said treatment and would look for optimal results with respect to the time period of the said treatment. Hence, the results provided in the instant Declaration is not seen as unexpected.



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***Conclusion***

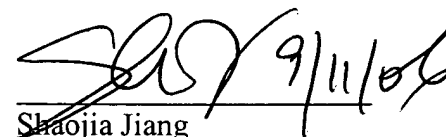
Claims 14-34, 38-53, 56-62, 64, 66, 68 and 70 are rejected

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GK

  
Shaojia Jiang  
Supervisory Patent Examiner  
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